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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE MEETING
INTERDISCIPLINARY ADVISORY COMMITTEE
Virtual, 4822 Madison Yards Way, Madison
Contact: Brad Wojciechowski (608) 266-2112
June 25, 2025

The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Committee.

AGENDA

9:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-2)

B. Approval of Minutes of April 30, 2025 (3)

C. Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements and Recognition – Discussion and Consideration

E. Administrative Matters – Discussion and Consideration

1. Department, Staff and Committee Updates
2. Election of Officers
3. Committee Members – Committee Member Status
    a. Englebert, Doug – Controlled Substances Board Representative
    b. Kane, Amanda K. – Board of Nursing Representative
    c. Schmeling, Gregory – Medical Examining Board Representative
    d. Streit, Tara E. – Physician Assistant Affiliated Credentialing Board Representative
    e. Watkins, Alexis – Cosmetology Examining Board Representative
    f. Weitekamp, John G. – Pharmacy Examining Board Representative
4. Alternates
    a. Bloom, Alan – Controlled Substances Board Representative
    b. Edwards, Jacqueline K. – Physician Assistant Affiliated Credentialing Board Representative
    c. Malak, Jennifer L. – Board of Nursing Representative
    d. McIntosh, Dana – Cosmetology Examining Board Representative
    e. Wilson, Christa M. – Pharmacy Examining Board Representative
    f. Yu, Emily S. – Medical Examining Board Representative

F. IV Hydration Clinics – Discussion and Consideration

1. Rules, Regulations and Guidance related to IV Hydration Clinics in Other States **(4-28)**
2. Draft IV Hydration Guidance Document **(29-35)**

G. Future Topics – Discussion and Consideration

H. Public Comments

ADJOURNMENT

NEXT MEETING: AUGUST 27, 2025

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
INTERDISCIPLINARY ADVISORY COMMITTEE
MEETING MINUTES
April 30, 2025

PRESENT: Doug Englebert, Amanda Kane, Gregory Schmeling, Tara Streit, Alexis Watkins *(arrived at 9:31 a.m.)*, John Weitekamp

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Renee Parton, Administrative Rule Coordinator; Brenda Taylor, Board Services Supervisor; and other DSPS Staff

CALL TO ORDER

Brad Wojciechowski, Executive Director, called the meeting to order at 9:30 a.m. A quorum of five (5) members was confirmed.

Alexis Watkins arrived at 9:31

ADOPTION OF AGENDA

MOTION: Gregory Schmeling moved, seconded by John Weitekamp, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF FEBRUARY 26, 2025

Amendments to the Minutes
Present: Englebert
Document Footer: 2025

MOTION: Tara Streit moved, seconded by Amanda Kane, to approve the Minutes of February 26, 2025, as amended. Motion carried unanimously.

MEDICAL AESTHETICS AND IV HYDRATION

Presentation by Dr. Jen Yeager, DNP, APNP, AGACNP-BC, CCRN - Co-Founder Wisconsin Aesthetic Providers Coalition

MOTION: Tara Streit moved, seconded by Amanda Kane, to acknowledge and thank Dr. Jen Yeager, Co-Founder Wisconsin Aesthetic Providers Coalition, for her appearance and presentation to the Interdisciplinary Advisory Committee. Motion carried unanimously.

ADJOURNMENT

MOTION: Amanda Kane moved, seconded by Gregory Schmeling, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:41 a.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		2) Date when request submitted: 06/13/25 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting
3) Name of Board, Committee, Council, Sections: Interdisciplinary Advisory Committee		
4) Meeting Date: 06/25/2025	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Rules, Regulations and Guidance related to IV Hydration Clinics in Other State – Discussion and Consideration
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? ☐ Yes ☒ No	9) Name of Case Advisor(s), if applicable:

10) Describe the issue and action that should be addressed:

Discussion and consideration of other states rules, regulations, and guidance related to IV hydration clinics.

11) Authorization

Whitney DeVoe	06/13/25
Signature of person making this request	Date
Supervisor (Only required for post agenda deadline items)	Date
Executive Director signature (Indicates approval for post agenda deadline items)	Date

Directions for including supporting documents:
1. This form should be saved with any other documents submitted to the Agenda Items folders.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

State Medical Board of Ohio | Board of Pharmacy | Board of Nursing

JOINT REGULATORY STATEMENT OF THE STATE MEDICAL BOARD OF OHIO, OHIO BOARD OF PHARMACY, AND OHIO BOARD OF NURSING REGARDING RETAIL IV THERAPY CLINICS

Date Issued: 5/15/2025

This statement highlights existing law and is intended for the benefit of practitioners and the public to promote better understanding of the laws governing the practice of medicine, nursing, and pharmacy.

Introduction

As with the rest of the country, the number of retail IV therapy clinics is increasing in Ohio. Many of the clinics are adopting business and/or practice models without realizing the selection, prescribing, preparation, and administration of IV therapy constitutes the practice of medicine, nursing, and pharmacy. Because of the concern over the proliferation of retail IV therapy clinics, the lack of any industry-specific guidelines, and the potential harm to the citizens of this state, the State Medical Board of Ohio, the Ohio Board of Pharmacy, and the Ohio Board of Nursing (collectively the "Boards") have issued this joint regulatory statement. This regulatory statement is based upon existing Ohio laws and rules governing the scope and standards of care and compounding of drugs that are performed by individuals within these clinics.

Description of Current Practices at Retail IV Therapy Clinics

A retail IV therapy clinic offers the administration of IV fluids through drip IV infusion tubing into a patient's vein. The type or composition of the IV fluids is selected from a menu of pre-selected mixtures ("cocktails") or additives to basic saline. Some common examples include amino acids, vitamin C and vitamin B complex, Myers' Cocktail (magnesium, calcium, vitamin B complex, and vitamin C), Toradol (ketorolac), famotidine, and ondansetron. The cocktails are often offered to patients for the treatment of conditions such as dehydration, migraine relief, hangover recovery, nausea, athletic recovery, appetite regulation, and inflammation support.

Generally, a patient will walk into the business, review the menu of treatment options, complete a health screening questionnaire, and undergo a precursory evaluation (including pulse oximetry, heart rate, blood pressure, review of medications, and allergies) with an employee who is not a prescriber, usually a registered nurse or a paramedic.[1] [2] The employee will then recommend an IV cocktail, with or without additives, based on the "protocol" established by a licensed prescriber, which could be a physician (MD/DO), APRN, or PA.[3] The employee prepares the IV cocktail and administers the IV therapy to the patient. The employee assesses the patient's treatment and observes any complications. Once the IV therapy is complete, the patient is then discharged.

In many instances, a registered nurse or paramedic may be the only licensed health care professional interacting with the patient or present at the facility. The Boards are concerned about whether qualified individuals are making appropriate diagnoses and preparing and administering these IVs in a sterile manner consistent with state law based upon their statutorily defined scopes of practice and are complying with all the laws governing the practice of medicine, nursing, and pharmacy.

Application of Pharmacist, Physician, PA, and APRN Scope of Practice to IV Therapy

Practice of Pharmacy - Compounding

Ohio law defines compounding as the preparation, mixing, assembling, packaging, and labeling of one or more drugs pursuant to a prescription issued by a licensed health

[1] The State Board of Emergency Medical, Fire, and Transportation Services (EMFTS) determines the scope of practice for all certified Ohio EMS providers. The Board also authorizes the services respective for each level of Ohio EMS certification within the Ohio EMS scope of practice. Please note that the administration of IV fluids has not been authorized by the EMFTS Board for certified Ohio emergency medical technicians (formerly EMT-Basics). The administration of medicated IV fluids has been authorized solely for certified Ohio paramedics and is not permitted for advanced emergency medical technicians (formerly EMT-Intermediates). For additional questions regarding permitted activities by paramedics within retail IV therapy clinics, please contact the EMFTS Board.

[2] Licensed practical nurses have limited and dependent authority to administer only certain types of IV fluids, and in retail IV therapy clinics the authority is predicated on the RN or physician's presence on site (See ORC 4723.18).

[3] "APRN" is used throughout to refer to CNPs, CNSs, and CNMs, but not CRNAs, as CRNAs do not have prescriptive authority outside of a hospital setting. In an IV clinic, a CRNA can only function as an RN and must follow those rules applicable to RNs.

professional authorized to prescribe drugs.[4] Compounding may only be performed by a licensed pharmacist or licensed health professional authorized to prescribe drugs.[5] [6] The preparation of IV cocktails as previously described is considered compounding under Ohio law and the clinic is required to obtain a license as a terminal distributor of dangerous drugs (TDDD) from the Ohio Board of Pharmacy.

While compounded drugs can serve an important medical need for certain patients, they may also present a risk to patients. Compounded drugs are not FDA approved. In other words, the FDA has not reviewed these drugs to evaluate their safety, effectiveness, or quality. Further, there have been instances when compounded medications - primarily those injectable/IV medications that are intended to be sterile - have endangered public health due to unsanitary conditions or improper storage.

Practice of Medicine – Examination, Evaluation, Diagnosis, and/or Assessment of Patients, as well as Prescribing/Ordering Drugs

The operation of a retail IV therapy clinic involves the practice of medicine, nursing, and pharmacy. The practice of these professions requires a license and adherence to a scope of practice established by Ohio law. A license to practice these professions is specific to the licensee and does not generally permit the delegation of their scope of practice to any other unlicensed person except under specific laws and rules. Only licensed prescribers may diagnose a patient, assess their symptoms, and prescribe/order the administration of sterile compounded medications.

The services provided by retail IV therapy clinics constitute the practice of medicine or osteopathic medicine. The practice of medicine includes examining or diagnosing patients as well as prescribing, advising, recommending, administering, or dispensing a drug or medicine, application, operation, or treatment, of whatever nature, “for the cure or relief of a wound, fracture or bodily injury, infirmity, or disease.”[7] Physicians and other prescribers

[4] See ORC 4729.01 (C)

[5] See ORC 4729.01, OAC 4729:7-2, OAC 4729:7-3

[6] The compounding of certain types of drugs in a clinic setting may be delegated to a nurse or nurses. However, a prescriber is required to verify the final product before it is administered to the patient or is required to be physically on-site if verified by a nurse (See OAC 4729:7-3-04)

[7] See ORC 4731.34 (A)

(APRN/PA) must follow the standard of care for their health care profession and are each responsible and accountable for their clinical decisions.

Only the following individuals may diagnose, treat, or prescribe IV medication:

(1) A physician licensed pursuant to Chapter 4731. of the Ohio Revised Code;
(2) A physician assistant, licensed under Chapter 4730. of the Ohio Revised Code, who holds a valid prescriber number issued by the State Medical Board of Ohio and who has been granted physician-delegated prescriptive authority for this purpose; or
(3) A certified nurse practitioner, certified nurse midwife, or clinical nurse specialist licensed pursuant to Chapter 4723. of the Ohio Revised Code.

Licensees of the State Medical Board of Ohio, the Ohio Board of Pharmacy, and the Ohio Board of Nursing are cautioned to practice within their statutorily defined scope of practice, comply with the clinic licensure requirements of the Ohio Board of Pharmacy, and to neither aid nor abet the unlicensed practice of others.

Legal Restrictions and Prohibitions on Protocols, Nurses, Paramedics, and Unlicensed Individuals

Use of Protocols for Administration of IV Therapy is Prohibited

The use of protocols (sometimes referred to as standing orders) for the recommendation, compounding, and administration of IV medications is not authorized under Ohio law. The Boards have observed clinics where a nurse or paramedic is making recommendations with the assistance of a protocol.

To address the appropriate use of protocols for drug administration, the Boards collaborated to develop OAC 4729:5-3-12. This rule was developed based upon an earlier joint regulatory statement issued by the Boards and authorizes the use of protocols in the following scenarios:

> *(1) The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the revised code to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual*

or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations include cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks;

(2) The administration of biologicals or vaccines to individuals for the purpose of preventing diseases;

(3) The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns;

(4) The administration of erythromycin for prevention of ophthalmia neonatorum; and

(5) The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in agency 4729. of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention.

None of the scenarios listed above apply to the administration of IV therapies provided by retail IV therapy clinics. Therefore, the use of protocols by a retail IV therapy clinic for this purpose would be considered a violation of Ohio law.

Diagnosis of Patient and Recommendation of IV Therapy by Nurse or Paramedic is Prohibited

The diagnosis of the patient's condition and the recommendation of IV therapy constitutes the practice of medicine. This act is outside the scope of practice for a nurse or paramedic. Only a physician, PA, or APRN has the statutory authority to diagnose a patient's condition and to make the decision to provide medication, by injection or otherwise, to a patient.

The discussion with the patient and recommendation of an IV and additives thereto, including "cocktails" and prescription drugs, are also outside the scope of practice of a registered nurse or paramedic. Only a licensed physician, PA, or APRN may diagnose a patient's condition and recommend IV treatment for the patient's condition.[8]

[8] See ORC 4731.34 (A), ORC 4730.20, and ORC 4723.43

While some retail IV therapy businesses have a physician owner, co-owner, investor, or associate, it has been reported that the physician or another licensed prescriber may not be the individual who actually evaluates the patient. Instead, a physician, PA, or APRN may be identified as "a medical director," "on staff," or "available," but it is only the nurse or paramedic who interacts with and treats the patient, aside from the patient's specific request for medications. This is insufficient to establish a valid practitioner-patient relationship, which is required before the administration of prescribed drugs.

Use of Unlicensed Individuals is Prohibited

Ohio laws prohibit a physician, PA, or APRN from delegating the administration of intravenous drugs or controlled substances to an unlicensed individual.[9] Further, ORC 4729.01 defines "drug" broadly to include any article or supplement to an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals. Cumulatively, these laws prohibit unlicensed persons from administering IV drugs at an IV clinic.

Standard of Care for Physicians, PAs, and APRNs

A physician, PA, or APRN must personally evaluate the patient, diagnose the patient, and make the treatment recommendations. The physician, PA, or APRN must further create a comprehensive medical record that complies with the standard of care. If the physician, PA, or APRN decides to prescribe IV therapy, that prescriber must issue a prescription or medication order, and only then may the IV therapy be administered. It is the obligation of the physician, PA, or APRN to exercise their medical judgment in determining that the treatment will actually benefit the patient and is for a legitimate medical purpose. A licensed person other than the physician, PA, or APRN may administer the IV only if administration of IVs is within that licensee's scope of practice.

In addition to creating a comprehensive medical record that complies with the standard of care, the prescriber must obtain informed consent and document it in the medical record prior to the delivery of care. It is important to recognize that obtaining informed consent is an educational process involving the patient in shared decision-making. In obtaining informed consent, the health care provider should assess the patient's ability to understand relevant

[9] See ORC 4731.053, ORC 4730.203, and ORC 4723.489

medical information and the implications of treatment alternatives and to make an independent, voluntary decision and present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. Information should include: (1) the diagnosis; (2) the nature and purpose of recommended interventions; (3) the burdens, risks, and expected benefits of all options, including forgoing treatment; (4) document the informed consent conversation, or written consent; and (5) the patient's decision in the medical record in some manner.

Use of Telehealth

The relationship between health care professionals, such as physicians, PAs, and APRNs, and a patient may be established via telehealth in accordance with ORC 4743.09 and telehealth rules implementing this section.[10] The Medical Board's telehealth rule in OAC 4731-37-01 is applicable to physicians as well as PAs and APRNs.

Pursuant to these telehealth laws and rules, a physician, PA, or APRN who establishes a prescriber-patient relationship via telehealth shall adhere to the same standard of care for telehealth visits as the standard of care for an in-person visit.

If a health care professional (physician, PA, or APRN) determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall see the patient in a reasonable timeframe or make the appropriate referral to another health care professional to meet the standard of care.[11]

When a telehealth visit is conducted by a health care professional, pursuant to OAC 4731-37-01, the health care professional shall comply with all standard of care requirements to provide telehealth services to a patient including, but not limited to:

(1) Verify the patient's identity and physical location in Ohio, communicate the health care professional's name and type of active Ohio license, and document this in the patient's medical records;
(2) Document the consent for telehealth treatment of the patient;

[10] See ORC 4723.94, ORC 4730.60, ORC 4731.741, OAC 4731-37-01, OAC 4731-11-09, OAC 4730-1-07 (B), and OAC 4723-8-02 (D)
[11] See OAC 4731-37-01 (B)(4)

(3) Comply with patient privacy and security requirements for the patient and their protected health information required by Ohio and federal law;
(4) Through interaction with the patient, the health care professional shall complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care for an in-person visit;
(5) Establish or confirm a diagnosis and treatment plan including documentation of the necessity for the utilization of a prescription drug;
(6) Document in the patient's medical record the consent for treatment, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities. The complete medical record shall be available to the patient and other treating health care professionals.

Further, physicians and PAs who hold a valid prescriber number issued by the State Medical Board of Ohio and who have been granted physician-delegated prescriptive authority may prescribe non-controlled drugs through telehealth provided that they comply with the requirements of OAC 4731-37-01 which include an appropriate medical evaluation through interaction with the patient. If the telehealth prescribing involves controlled substances, the physician or PA must also comply with state and federal laws and rules regarding the prescription of controlled substances, including the requirements in OAC 4731-11-09.

The prescriptive authority of PAs and APRNs shall not exceed the prescriptive authority of the supervising or collaborating physician respectively and shall comply with all applicable state and federal laws and regulations.

Additional Legal and Scope of Practice Requirements

Compliance with Prescriber Compounding Rules

As previously stated, the addition of drugs or vitamins to an IV solution is considered compounding under Ohio law and requires the clinic to obtain a license as a terminal distributor of dangerous drugs (TDDD) from the Ohio Board of Pharmacy. While there are some exceptions to Ohio Board of Pharmacy licensure for clinics that possess prescription medications (referred to in law as dangerous drugs), those exceptions do not apply if the clinic is engaged in sterile drug compounding. This means that retail IV therapy clinics are

required to be licensed and comply with Ohio's prescriber compounding rules established by the Ohio Board of Pharmacy.

Generally, the compounding of IVs can be done under the Ohio Board of Pharmacy's immediate-use rule[12] if the sterile compounding involves not more than two entries into any one package (e.g., bag, vial) of sterile infusion solution or administration container/device using commercially manufactured sterile, non-hazardous drugs from the manufacturer's original container. Additionally, any IV prepared under this rule must be administered no later than six hours following preparation of the drug. Other compounding activities may require compliance with more advanced compounding standards, including USP 797 (see table 1).

Table 1. Ohio Prescriber Compounding Requirements[13]

Type of Drug Preparation	Compounding	Requirements
Admixing or compounding NO MORE than three commercial products and NO MORE than two entries into any one container.	Immediate Use	Comply with OAC 4729:7-3-04 Beyond-Use Date: 6 hours following preparation Compounding must be prepared in a designated clean medication area. Prohibits anticipatory compounding (compounding in advance) Prohibits personally furnishing of compounded products A licensed prescriber is on-site and immediately available
Admixing or compounding more than three commercial products or more than two	Compounding (Medium Risk/ Category 2 CSP)	Comply with OAC 4729:7-3-03 and USP 797 Compliance

[12] See OAC 4729:7-3-04

[13] For more information on prescriber compounding requirements, visit: www.pharmacy.ohio.gov/prescribercomp.

entries into any one container.		A licensed prescriber is on-site and immediately available
Repackaging and relabeling sterile products to individual doses.	Compounding (Medium Risk/ Category 2 CSP)	Comply with OAC 4729:7-3-03 and USP 797 Compliance A licensed prescriber is on-site and immediately available
Admixing or compounding a nonsterile powder to use as sterile injection.	Compounding (High Risk/ Category 3 CSP)	Comply with OAC 4729:7-3-03 and USP 797 Compliance A licensed prescriber is on-site and immediately available
Reconstitution NOT according to manufacturer's labeling (i.e. using other diluents or amounts of diluents).	Compounding (Immediate Use or Low Risk/ Category 1 CSP)	Comply with OAC 4729:7-3-04 or USP 797 Compliance A licensed prescriber is on-site and immediately available
Reconstitution according to the manufacturer's labeling.	This is not considered compounding under Ohio law	Use aseptic technique

The compounding of drugs in a prescriber setting may be delegated to a nurse or nurses. However, a prescriber is required to verify the final product before it is administered to the patient or is required to be physically on-site if verified by a nurse. Unlike a nurse, a paramedic is not permitted to independently verify a compounded medication prior to administration under any circumstances. Failure to adhere to these standards is considered a violation of Ohio law and could subject the clinic to administrative discipline.

Please be advised that a full list of the requirements for prescriber compounding can be found in the Ohio Board of Pharmacy's prescriber compounding inspection guide that can be accessed by visiting: www.pharmacy.ohio.gov/prescribercomp.

As part of the Ohio Board of Pharmacy's TDDD licensing process, each license is required to have a responsible person at all times. By rule, the responsible person on the TDDD license is responsible for compliance with all state and federal laws, regulations, and rules governing

the distribution of dangerous drugs. The Board of Pharmacy is growing concerned that those who agree to serve as the responsible person on a TDDD license are not exercising an appropriate level of supervision of the activities of the clinic. The rules require the responsible person to be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.[14] For example, some licensees have responsible persons listed who are not physically located in the state. Having a responsible person "in name only" puts the clinic, staff, and patients at risk and may subject the clinic and the responsible person to administrative discipline.

Regardless of the ownership structure of the retail IV therapy clinic, neither the business nor the business owner is permitted to exercise any control over the way physicians and other health care professionals provide medical, nursing, or pharmacy services. Owners cannot interfere with the responsible person's obligation to ensure compliance with the law, nor the medical judgment of prescribers employed by the clinic. Physicians and other prescribers are cautioned to understand Ohio laws and rules before entering employment or partnership with these and similar businesses, especially if they agree to serve as the responsible person on the clinic's TDDD license.

Lastly, a retail IV therapy clinic is only permitted to purchase drugs from Ohio Board of Pharmacy license holders. To ensure that a clinic is purchasing from a licensed drug distributor (e.g., wholesaler, manufacturer, outsourcing facility, etc.), each TDDD is required, per OAC 4729:5-3-04, to verify the seller is appropriately licensed with the Ohio Board of Pharmacy. This verification, which can be performed using Ohio's eLicense system, must be done prior to an initial purchase and then annually if the clinic continues to purchase from that drug distributor. By verifying a supplier is legally authorized to sell drugs in Ohio, licensees can avoid the purchase of counterfeit medications. For more information about avoiding counterfeit medications, visit: www.pharmacy.ohio.gov/counterfeit.

Ohio Board of Nursing and the Nurse Practice Act

The Ohio Board of Nursing joins with the State Medical Board of Ohio and the Ohio Board of Pharmacy in their concern about the rise of retail IV therapy clinics and the possibility that nurses are working outside the confines of the laws and rules of the Boards. Specifically, the

[14] See OAC 4729:5-2-01

Board of Nursing is concerned that nursing licensees participating in retail IV therapy may be practicing beyond their scope and without the proper steps in place to ensure safe and legal administration.

IV therapy is a complex, learned skill. Registered nurses (RNs) and APRNs choosing to provide this therapy must ensure they are properly educated and fully compliant with all the requirements under the law.

LPNs

A licensed practical nurse (LPN) is not authorized to administer IV solutions at a retail IV therapy clinic. While an LPN may administer some IV solutions[15] for individuals aged eighteen or older and only when directed to do so by a licensed physician, physician assistant, dentist, optometrist, podiatrist, or registered nurse in accordance with ORC 4723.18, they are not permitted to initiate the administration of IV solutions containing vitamins or electrolytes.[16] Therefore, utilizing an LPN to initiate an IV therapy containing the additives is not permissible.

RNs

A registered nurse (RN) can only administer intravenous fluids, nutrient therapies, vitamin infusions, and medications after obtaining a valid prescription or order that was issued by a physician, PA, or APRN. The prescription or order must be part of a medically prescribed plan of care that includes a personal examination and a bona fide patient relationship. "Protocols," as discussed previously in this document, are not permitted under Ohio law. An RN cannot order IV hydration fluids and cannot determine the dosage, route, or frequency.[17]

An RN may engage in the preparation of a compounded IV therapy.[18] However, a prescriber is required to verify the final product prior to administration or is required to be physically

[15] Five per cent dextrose and water; five per cent dextrose and lactated ringers; five per cent dextrose and normal saline; normal saline; lactated ringers; 0.45 per cent sodium chloride and water; 0.2 per cent sodium chloride and water; or 0.3 per cent sodium chloride and water.

[16] An LPN is not permitted to administer IV solutions containing vitamins or electrolytes unless a registered nurse initiates the first infusion of the solution containing vitamins or electrolytes.

[17] See ORC 4723.151(A)

[18] See OAC 4729:7-3

present on site to answer any questions the nurse may have regarding the compounding process.[19]

An RN administering IV therapy must have the knowledge, skill, and competency necessary to carry out the administration procedures and monitor the client in a safe manner. An RN should perform a nursing assessment of the patient to include vital signs. An RN should monitor the patient while the patient undergoes the IV administration. The RN should monitor the patient for such things as side effects, toxic effects, allergic reactions, unusual and unexpected effects, changes in a client's condition that contraindicate continued administration of the pharmaceutical or treatment regimen, those effects that may rapidly endanger a client's life or well-being, and must be prepared to make judgments and decisions concerning actions to take in the event such effects occur.

An RN is expected to document all nursing acts performed by the RN in carrying out the IV administration and noted during the monitoring of the patient during administration.

APRNs

APRNs are held to the same standard as a physician or PA working in a retail IV hydration clinic. An APRN must have the appropriate prescriptive authority to prescribe medications under Ohio law and in accordance with the standards set forth in this statement.

APRNs should carefully review the portion of this statement applicable to prescribers to understand their obligations while working in a retail IV therapy clinic. An APRN must also include a retail IV therapy clinic as part of their collaborative agreement prior to undertaking this role.

Physician Agreements with PAs and APRNs

A PA must have a signed supervision agreement with a physician licensed in Ohio to provide services to patients located in Ohio including in a retail IV therapy clinic.[20] The physician shall supervise the services provided by the PA and only allow the PA to perform services that are within the physician's normal course of practice and expertise.[21]

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[19] See OAC 4729:7-3-04

[20] See ORC 4730.19

[21] See ORC 4730.02

The physician shall be continuously available for direct communication with the PA by either being physically present at the location where the PA is practicing or being readily available through telecommunication and being in a location that is a distance from the location where the PA is practicing "that reasonably allows the physician to assure proper care of patients." A physician may not supervise more than five (5) PAs at any one time.[22]

The physician shall personally and actively review the PA's activities, and also establish a quality assurance system which, among other activities, requires the physician to routinely review patient records and PA orders regarding selected patients.[23] The physician and PA are required to have a copy of the supervision agreement and records of the required quality assurance activities.[24]

Similarly, an APRN must have a written standard care arrangement with a physician licensed in Ohio to provide services anywhere, including in a retail IV therapy clinic.[25] The physician that the APRN is collaborating with must be licensed in Ohio and must be practicing in a specialty that is the same as or similar to the APRN's specialty.[26]

Likewise, the physician with whom the APRN has entered into a standard care arrangement must be continuously available to communicate either in person or by electronic means.[27] A physician may not collaborate with more than five (5) APRNs in the prescribing component of their practices.[28] A physician and APRN in a standard care arrangement must participate in a quality assurance process that includes periodic random chart review, which includes review of prescribing patterns.[29]

CONCLUSION

The diagnosis of a condition that results in the ordering of IV-delivered drugs, amino acids, or vitamins is the practice of medicine and the preparation of these drugs is considered drug compounding. Failure to obtain licensure as a terminal distributor of dangerous drugs is a

[22] See ORC 4730.21
[23] See ORC 4730.21
[24] See ORC 4730.19 and ORC 4730.21
[25] See ORC 4731.27 and ORC 4723.431
[26] See ORC 4723.431
[27] See ORC 4723.01
[28] See ORC 4723.431
[29] See OAC 4723-8-05

violation of Ohio law and may subject a retail IV therapy clinic to administrative and/or criminal penalties. Meanwhile, the failure of licensees to follow the laws and rules governing their practice(s) could result in disciplinary proceedings and sanctions by their respective boards; by law, sanctions may include monetary fines, probation of a license, suspension of a license, or even revocation of a license, as set forth in each of the practice acts.

Most important, however, is the safety of Ohio patients who seek IV treatment through these clinics. Patients must be evaluated by an appropriate practitioner. The IV medications must be compounded in a safe and sterile environment. Administration of the IV must be done by those with the education, training, and skills to do so. Each of these roles in the process requires that the individual be licensed and requires them to carry out their obligations in the same manner that is required of them for any other task within their scope of practice. Each of the Boards is dedicated to ensuring the law in these areas of practice is followed, as that is how the public is best protected.

NEBRASKA
Good Life. Great Mission.
DEPT. OF HEALTH AND HUMAN SERVICES

Nebraska Board of Nursing

ADVISORY OPINION

OPINION: IV/ Infusion Therapy
ADOPTED: 11/2023
REVISED:
REAFFIRMED:

This Nebraska Board of Nursing advisory opinion is issued in accordance with the Nebraska Nurse Practice Act, Neb. Rev. Stat. 38-2216 (2). As such, this advisory opinion is for informational purposes only and is non-binding. The advisory opinions define acts, which in the opinion of the board, are or are not permitted in the practice of nursing.

IV/Infusion Therapy

Summary
The Intravenous (IV)/Infusion Therapy Standards of Practice apply to any patient population and setting where vascular access devices are inserted and/or managed and where infusion therapies are administered.

1. A nurse, Licensed Practical Nurse (LPN), Registered Nurse (RN), Advanced Practice Registered Nurse (APRN) must only assume those duties and responsibilities within the scope of practice for which the nurse has the necessary knowledge, skills and abilities.
2. Nurses are expected to engage in the practice of nursing in accordance with accepted standards of practice as well as applicable statutes and regulations.
3. An order from a licensed practitioner (LP) Medical Doctor (MD), Doctor of Osteopathy (DO), Physician Assistant (PA), APRN to administer medication or IV therapy (including hydration) is required before a nurse may provide such services.
4. A nurse (LPN or RN) may not diagnose a health condition, prescribe, or order a treatment or medication, or perform acts that require a different license to practice another profession.
5. It is within the scope of practice of a nurse to administer IV therapy, pursuant to an order from a (LP), commensurate with a nurse's licensure level.
6. Every nurse is responsible to ensure their own competency to perform these activities consistent with their educational preparation and experience. Additionally, a licensed practical nurse must meet the requirements of Neb. Rev. Stat. §38-2237.
7. **Pursuant to 172 NAC 99-002 and 004.02(C) a nurse may not delegate or assign to an unlicensed individual, the administration of IV therapy**.
8. Only an authorized practitioner (Neb.Rev. Stat 38-2850) may compound drugs for use in IV therapy.
9. The introduction of different components or drugs into an IV solution is compounding and is not within the scope of practice of a nurse.
10. A licensed provider is responsible for ensuring all orders and/or prescriptions are within their licensed scope of practice.

Statutes

LPN – Licensed Practical Nurse

Neb. Rev. Stat. § 38-2211 provides "(1) Practice of nursing by a licensed practical nurse means the assumption of responsibilities and accountability for nursing practice in accordance with knowledge and skills acquired through an approved program of practical nursing. A licensed practical nurse may function at the direction of a licensed practitioner or a registered nurse. (2) Such responsibilities and performances of acts must utilize procedures leading to predictable outcomes and must include, but not be limited to:(a) Contributing to the assessment of the health status of individuals and groups; (b) Participating in the development and modification of a plan of care; (c) Implementing the appropriate aspects of the plan of care; (d) Maintaining safe and effective nursing care rendered directly or indirectly; (e) Participating in the evaluation of response to interventions; (f) Providing IV therapy if the licensed practical nurse meets the requirements of section 38-2237; (g) Assigning and directing nursing interventions that may be performed by others and that do not conflict with the Nurse Practice Act."

RN – Registered Nurse

Neb. Rev. Stat. § 38-2212 provides "(1) The practice of nursing by a registered nurse means assuming responsibility and accountability for nursing actions. (2) Nursing actions include, but are not limited to: (a) Assessing human responses to actual or potential health conditions; (b) Establishing nursing diagnoses; (c) Establishing goals and outcomes to meet identified health care needs; (d) Establishing and maintaining a plan of care; (e) Prescribing nursing interventions to implement the plan of care; (f) Implementing the plan of care; (g) Teaching health care practices; (h) Delegating, directing, or assigning nursing interventions that may be performed by others and that do not conflict with the Nurse Practice Act; (i) Maintaining safe and effective nursing care rendered directly or indirectly; (j) Evaluating responses to interventions, including, but not limited to, performing physical and psychological assessments of patients under restraint and seclusion as required by federal law, if the registered nurse has been trained in the use of emergency safety intervention; (k) Teaching theory and practice of nursing; (l) Conducting, evaluating, and utilizing nursing research; (m) Administering, managing, and supervising the practice of nursing; and (n) Collaborating with other health professionals in the management of health care.

APRN - NP-Nurse Practitioner

Neb. Rev. Stat. §38-2315 provides "(1) A nurse practitioner may provide health care services within specialty areas.…"

Neb. Rev. Stat. § 38-2312 defines a nurse practitioner as "…a registered nurse certified as described in section 38-2317 and licensed under the Advanced Practice Registered Nurse Practice Act to practice as a nurse practitioner.

APRN -CRNA Certified Registered Nurse Anesthetist

Neb.Rev.Stat §38-706 and §38-707

APRN -CNM Certified Nurse Midwife

Neb. Rev. Stat §38-613

APRN-CNS Clinical Nurse Specialist
Neb. Rev Stat §38-905 and 38-906

LP – Licensed Practitioner
Neb. Rev. Stat. § 38-2209 defines a licensed practitioner as "…a person lawfully authorized to prescribe medications or treatments." For additional information refer to the Team Nursing Advisory.

Compounding
Neb. Rev. Stat. §38-2867 defines an authorized practitioner as a pharmacist, a pharmacy intern, and a practitioner with a pharmacy license.
Neb. Rev. Stat. §38-2811 defines compounding as "…the preparation of components into a drug product."
Neb. Rev. Stat. §38-2867.01 sets out how and when an authorized practitioner may compound a drug product, what constitutes compounding and what is not considered compounding under state law, and when compounding is prohibited under state law.
Federal law also addresses compounding, and the federal Food and Drug Administration has issued guidance on many of the issues related to compounding. More information on compounding can be found at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

Discussion
All nurses licensed to practice nursing in Nebraska must practice in compliance with the Uniform Credentialing Act, the Nurse Practice Act, regulations adopted under those Acts, as well as other statutes and regulations, if any, pertinent to the setting where practice occurs. Registered Nurses (RN), Licensed Practice Nurses (LPN), and Advanced Practice Registered Nurses (APRN) are accountable for the provision of safe competent nursing care in all practice settings.

Nurse Practitioners have authority to prescribe and/or administer medications or treatments within their specialty area of practice under their own license. Certified Nurse Midwives (CNM)s and Certified Registered Nurse Anesthetist (CRNA) s have authority to prescribe medications or treatments as permitted by their licenses' scopes of practice. Clinical Nurse Specialists (CNS) do not have prescriptive authority.

Upon receipt of an order from a LP and in collaboration with that LP, the nurse (LPN or RN) may perform infusion therapy as part of an overall comprehensive plan of care to treat various conditions.

IV/infusion therapy is a complex, learned skill and there are many considerations necessary to ensure the safe performance of this skill inside or outside of a traditional facility setting. IV / infusion therapy involves procedures that are complex nursing interventions (**172 NAC 99-002 and 004.02(C)) and may not be delegated or assigned by RNs or by LPs or assigned by LPNs to unlicensed persons.** IV/infusion therapy includes assessment, placement of the IV, delivery and monitoring of the therapy, and all related activities.

Practice guidance
All medications must be obtained in compliance with both federal and state laws, which include The Wholesale Drug Distributor Licensing Act, statutes governing the practice of pharmacy, the federal Drug Supply Chain Security Act, and the federal Compounding Quality Act, among others and their implementing regulations. These statutes govern who may distribute human drugs, the compounding of drugs for human use, licensing requirements, and the tracing of drugs within the supply chain. Regulations have been adopted by the state and federal government under these Acts, as applicable.

Prior to providing IV/infusion therapy, a systematic patient assessment must be performed and documented by a licensed provider (LP). The RN may gather information for the patient assessment and then provide that information to the LP. The LPN may participate in the assessment by obtaining information about a patient's basic health status from the patient, their records and related health data and by providing that information to the RN or LP.

Once the assessment is reviewed by the LP, appropriate intervention (medication(s) or treatment(s)) may be ordered by the LP. A written plan should be in place to address what steps need to be taken if a nurse has questions about an order for therapy or there is an emergency or an adverse reaction. The nurse (LPN or RN) must check the order for administration directions and signature from the LP and follow the five rights for providing medication when performing the therapy.

Once the treatment is given or being given, the patient must be monitored by the RN or LPN or LP for adverse reactions to treatment. If there are adverse reactions, those must be documented and communicated to the LP, if the nurse is the RN; the LPN reports to the RN or LP.

Documentation
The nurse must maintain standard nursing documentation including at least the following:

- Patient assessment and medical history data;
- Education provided to the patient on the prescribed IV therapy;
- Presence of signed informed consent for procedure(s);
- Written pre and post IV infusion education;
- Nursing assessments, notes and orders;
- Specific procedures performed and patient's response to procedure;
- Patient reactions to the IV therapy, and interventions required to mitigate or correct adverse outcomes, AND
- Post IV infusion care instructions, signs and symptoms to seek medical care if emergency presents itself, and recommended follow-up or when to contact the LP.

Evaluation
The nurse is responsible for the monitoring and documentation of the client, the encounter, the IV mix provided and the client's tolerance of the IV/infusion therapy product provided. The nurse is further responsible for the documentation of the visit.

Practice Alignment

LPN/RN

Nurses – Registered Nurses and Licensed Practical Nurses

LPNs function in the healthcare team in a directed role. RNs direct LPN practice and duties, however neither RN nor LPN may: diagnose, prescribe, or order a medication or treatment, dispense drugs or mix/compound components for IV / infusion therapy.

Consistent with their scope of practice and with organizational policy and procedure, and ongoing competencies **LPN and RNs** practice may include:

- Short and midline peripheral IV device insertion and removal;
- Use of adjunct aids such as ultrasound for vein identification and selection.
- Use of an existing IV or other infusion device for the administration of medication, hydration, nutrition, blood products, or obtaining a blood sample.
- Monitoring the patient.
- Maintenance of the infusion site.
- Infusion of an IV solution where medication is compounded (prepared, mixed, packaged and labeled) in accordance with federal and state laws and regulations; and
- Reconstitution and admixture of a solo medication with an IV solution in accordance with manufacturer instructions—is not considered compounding.

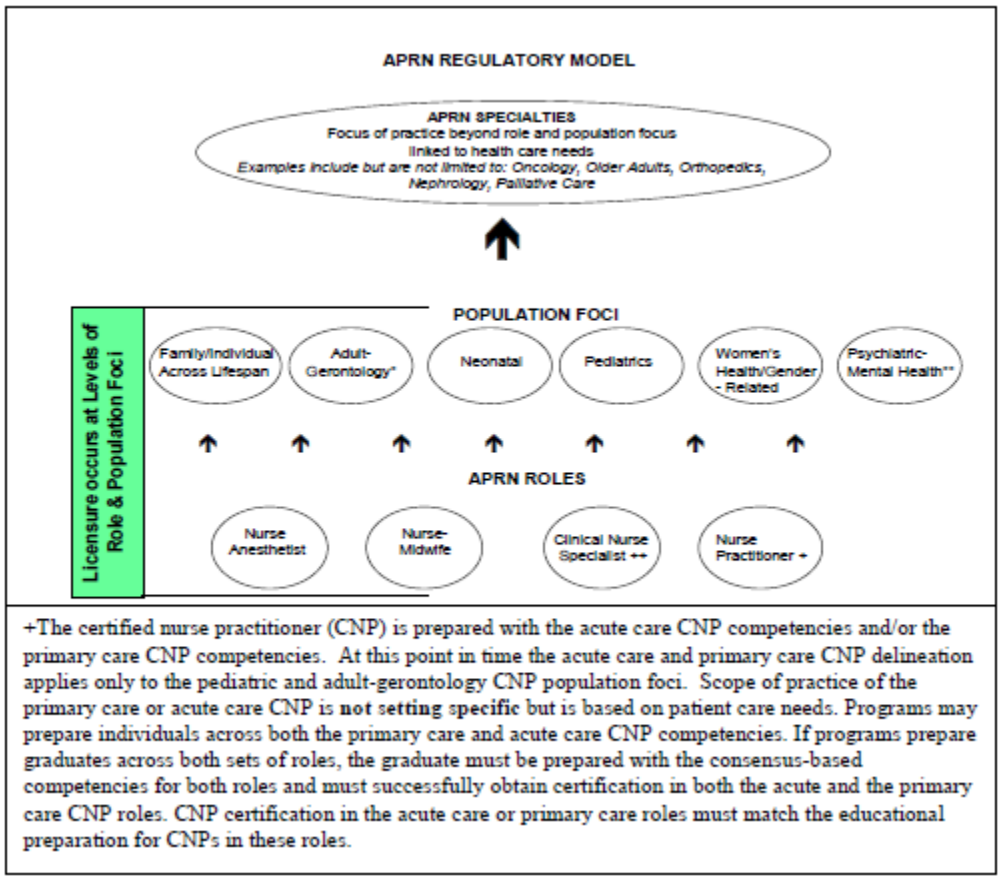
APRN

Nurse Practitioners

NPs as advanced practice registered nurses (APRNs) bear full accountability for practice that is aligned with graduate education, board certification and licensed practice role with one or more population foci.

38-2315. Nurse practitioner; functions; scope.

The fundamental premise of practice alignment is that the APRN has the knowledge to differentially diagnose and manage most conditions/potential adverse outcomes that will be encountered for a particular patient population (Buppert, 2017). Advanced practice nurses have the added skills of diagnosing, treating, and prescriptive authority. Practice alignment necessarily precedes procedural competencies.



(Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education July 7, 2008)

Specialty Practice

Specialty/Subspecialty Practice

A nursing specialty encompasses a specific area of discrete study, research, and practice as defined and recognized by the profession (ANA, 2017). Competencies for nursing specialty practice build upon core nursing skills required for entry into practice. RNs entering practice are encouraged to practice for at least one year to gain knowledge and develop skills associated with basic medical and surgical principles.

Nurses are encouraged to seek guidance and professional alignment with groups who concentrate on IV therapy and IV access. Organizations such as: Infusion Nurses Society or the National Infusion Center Association. These organizations set the standards for IV therapy in the traditional medical environment. Nurses of all levels of licensure are responsible for providing care safely and appropriately.

Education/Training

Education and Training

Education and training, while important in the development of competency, does **not** expand nursing scope of practice. Nursing specialties rely on professional practice associations as the stewards of specialty nursing scope and standards of practice for focused practice competencies (ANA, 2017).

Various titles and certificates of achievement conferred by vendors and commercial education entities, notwithstanding that the latter have a place in the acquisition of knowledge and competencies for IV hydration procedures, are **not** a substitute for peer reviewed (DHHS, 2019) courses and continuing education, and board certification by professional nursing specialty practice associations. Additional education does not expand the scope of practice of a licensee.

Training

For infusion therapy:

1. Documentation of current clinical competency to perform procedure
2. Initial and ongoing competence as evidenced by documented completion of didactic and clinical continuing education programs, employing agency education programs, and/or certification by a recognized body of infusion therapy experts in the following:
    - Pre-insertion assessment and placement
    - Ongoing assessment and monitoring of indwelling catheter
    - Infection prevention and standard precautions including hand hygiene and the use of appropriate personal protective equipment (PPE)
    - Identification, prevention, and management of complications
    - Patient /caregiver education including the prescribed infusion therapy, the overall plan of care, the goals of treatment, self-monitoring for signs and symptoms of infusion-related complications and how to access health care services as needed
    - Use of technical and medical equipment required for medication preparation and/or administration
    - Removal of catheter
    - Documentation of assessment, insertion, response to treatment and removal, as applicable
    - Surveillance/quality improvement/outcome measure participation and contribution
    - Use of adjunct aids such as ultrasound for vein identification and selection when applicable.

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State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		2) Date when request submitted: 6/18/25 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Interdisciplinary Advisory Committee			
4) Meeting Date: 06/25/2025	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Discussion and Consideration –Draft IV Hydration Guidance Document	
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? ☐ Yes ☒ No	9) Name of Case Advisor(s), if applicable:	
10) Describe the issue and action that should be addressed: Discussion and consideration of the draft of the IV hydration guidance document.			
11) Authorization Whitney DeVoe — 06/18/25 Signature of person making this request — Date Supervisor (Only required for post agenda deadline items) — Date Executive Director signature (Indicates approval for post agenda deadline items) — Date			
Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the Agenda Items folders. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

JOINT ADVISORY OPINION OF THE WISCONSIN EXAMINING BOARDS OF MEDICAL, NURSING, PHARMACY, AND COSMETOLOGY, AND THE PHYSICIAN ASSISTANT AFFLIATED CREDENTIALING BOARD, AND THE WISCONSIN CONTROLLED SUBSTANCES BOARD

It is the overall duty of each Examining Board to improve the profession they supervise, both within and outside its own profession, to bring about a better relationship between the profession and the general welfare of this state. Each Examining Board is empowered to set standards of professional competency and conduct for the profession it supervises. With these principles in mind, the Interdisciplinary Advisory Committee (Committee) consisting of the Wisconsin Medical Examining Board, Pharmacy Examining Board, Board of Nursing, Physician Assistant Affiliated Credentialing Board, Cosmetology Examining Board and Controlled Substances Board was established to discuss issues of mutual concern.

In recent years, Wisconsin has seen an increase in the intravenous (IV) hydration therapy business and the Wisconsin Department of Safety and Professional Services (DSPS) has seen an increase in questions from healthcare professionals concerning the legal requirements for IV hydration therapy businesses.

IV hydration therapy businesses provide patients with IV fluids with or without prescription medications, vitamins, minerals and/or amino acids. Based on inquiries received by DSPS, there appears to be confusion among healthcare professionals and the public as it relates to understanding the responsibilities of healthcare professionals engaged in these businesses. Because of the concern over the lack of any industry-specific guidelines or laws regarding the operation of these businesses and the potential harm to the residents of Wisconsin, the Committee puts forth this guidance document. This guidance document is based upon the existing laws of Wisconsin and sets forth the relevant laws and standards of care implicated by IV hydration therapy businesses within the context of a retail or "on-demand" business setting.[1]

For purposes of this guidance document, the Committee has divided the practice occurring at IV hydration businesses into three main stages: assessment, compounding, and administration. The guidance below is meant to assist licensees in understanding the laws and regulations implicated at each stage. Please note, this is not an exhaustive list, but rather a list addressing the most commonly raised practice concerns.

BACKGROUND

Prior to discussion of the specific stages, the Committee believes it is crucial to highlight that services offered by IV hydration therapy businesses constitute the practice of medicine and surgery.

The practice of medicine and surgery is defined as meaning:

[1] This guidance is meant to specifically address the emerging market for IV Hydration therapy or businesses offering IV Hydration therapy services. Underlying principles established in this guidance may be applicable to other services offered by healthcare professionals. Please contact private counsel to review your specific business model for compliance with relevant laws and regulations.

> [t]o examine into the fact, condition or cause of human health or disease, or to treat, operate, prescribe or advise for the same, by any means or instrumentality … [t]o apply principles or techniques of medical sciences in the diagnosis or prevention of any of the conditions described in par. (a) and in sub. (2) … [t]o penetrate, pierce or sever the tissues of a human being … [t]o offer, undertake, attempt or do or hold oneself out in any manner as able to do any of the acts described in this subsection.

See Wis. Stat. § 448.01(9). Further, pursuant to Wis. Stat. § 448.03, "[n]o person may practice medicine or surgery, or attempt to do so or make a representation as authorized to do so, without a license to practice medicine or surgery" except for "[a]ny person lawfully practicing within the scope of a license, permit, registration, certificate, or certification granted to practice… professional or practical nursing or nurse-midwifery under ch. 441… to practice as a physician assistant under subch. IX… or as otherwise provided by statute."

At its core, the IV hydration therapy business model involves offering patients, including on a walk-in basis, a menu of pre-selected mixtures ("cocktails") of additives to basic IV saline. The cocktails may include fluids with or without prescription medications, vitamins, minerals and/or amino acids. Some basic health screening generally occurs prior to the selection and administration of the IV. It is of concern to the Committee that the basic health screening and selection of IVs are being performed by unlicensed individuals or licensees whose scope of practice does not allow for the practice of medicine or surgery.

Although many IV hydration therapy businesses may have a physician, physician assistant (PA) or advanced practice nurse prescriber (APNP) associated with the business, in some instances a registered nurse (RN) may be the only licensed health care professional interacting with the patient. The Committee wants to make clear that a registered nurse (RN), or any individual not holding the proper credential, undertaking the diagnosing and prescribing of medications falls outside an RN's scope of practice[2] and can result in disciplinary action against not only the RN's license, but also the physician, PA, or APNP overseeing the practice.

Moreover, IV hydration therapy fluids and additives are prescription drugs requiring purchase and storage by a qualified practitioner which may include a physician, PA, or APNP. Fluids and additives must be purchased from FDA licensed manufacturers, distributors licensed in the state where they are being purchased, or from compounding pharmacies designated and licensed as 503B compounding facilities. Non-qualified individuals, including, but not limited to RNs or licensed practical nurses (LPNs), may not possess or store prescription drugs in any location not appropriately licensed by the Pharmacy Examining Board.

[2] It is not within the scope of practice for an RN or LPN to independently engage in acts that require independent medical diagnosis, or the ordering, compounding, or prescribing of IV fluids, IV medications, or IV therapeutic regimens. See Wis. Stat. § 441.001(4) and Wis. Admin. Code § N 6.03.

ASSESSMENT

The patient must be assessed prior to ordering any IV Hydration treatment. Practitioners who may order treatment appropriate to their area of competence as established by their education, training, or experience include:

- A physician licensed to practice medicine and surgery in this state as defined in Wis. Stat. § 448.01(5).
- A PA licensed pursuant to Wis. Stat. § 448.974.
- An APNP licensed pursuant to Wis. Stat. § 441.16.

Although telehealth may be utilized to perform the initial patient assessment, it is the recommendation of this Committee that patient assessment should be done in person, as a complete medical assessment is difficult to conduct via telehealth.[3] Certain conditions may be hard to evaluate without an in-person assessment including an assessment of necessary organ systems. An assessment consisting merely of a simple questionnaire without an appropriate clinical assessment would not meet the standard of care and is considered unprofessional conduct pursuant to Wis. Admin. Code § Med 24.07(2). A patient assessment should include at minimum a history and physical exam. Although a nurse may complete certain delegated portions of the assessment, a patient assessment should not rely solely on findings from a nursing assessment.

As part of the assessment, the practitioner may diagnose the patient's condition and make recommendations consistent with the findings from the history and physical as to treatment. Treatment recommendations may include a discussion with the patient surrounding which therapies, including the addition of specific additives, may be appropriate to treat the patient's condition. These discussions should include a description of risks, benefits and alternative options. To be clear, this constitutes the practice of medicine and should only be undertaken by a practitioner with statutory authority to diagnose and treat. The discussion with a patient and recommendation shall be provided by the practitioner.

Following the assessment, the practitioner may prescribe the appropriate therapy or treatment. The use of standing orders outside of an established practitioner-patient relationship for an individualized assessment, diagnosis and treatment of patients may be considered prescribing in a manner inconsistent with the standard of minimal competence pursuant to Wis. Admin. Code § Med 10.03(2)(c).

To ensure the assessment complies with the standard of care, after evaluating the patient and making treatment recommendations, a comprehensive medical record must be created. Additionally, informed consent shall be obtained to be consistent with the standard of care. Informed consent should include, but not be limited to, the risks of additives to saline, the risks of IV fluids, and the risks of an IV itself. Medical records must be stored in compliance with state and federal law, including those with the Wisconsin Department of Health Services.

[3] Telehealth is only acceptable if it meets established regulations. See Wis. Admin. Code chs. Med 24, PA 3 and N 8.

COMPOUNDING

After determining a course of treatment, a cocktail containing the additives ordered may need to be prepared. When an individual adds medications, vitamins, minerals and/or amino acids to IV bags, they are engaging in the practice of compounding, and federal and state law including section 503A of the Food, Drug, and Cosmetic Act apply. Application of these laws help ensure patients receive their treatment in sanitary conditions.

Pursuant to Wis. Stat. § 450.01(16), the practice of pharmacy includes the compounding, packaging, and labeling of drugs and devices. Further, pursuant to Wis. Stat. § 450.01(3), compound "means to mix, combine or put together various ingredients or drugs for the purpose of dispensing." Federal law allows either a licensed pharmacist or a physician to perform compounding.

The United States Pharmacopeia (USP) is the recognized publication that contains standardized requirements for compounding, including sterile compounding found in USP <797> and has been adopted by the FDA and the Wisconsin Pharmacy Examining Board as the enforceable standard. USP <797> applies to all individuals who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients.

The utilization of the "immediate use" provision of USP <797> does not circumvent USP sterile compounding requirements. Additionally, the "immediate use" provision requires certain conditions be met, including,

- Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
- Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
- The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
- The preparation involves not more than 3 different sterile products. **Please note, Saline Solution utilized in IV Hydration is a sterile product and must be included in this analysis.**
- Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
- Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
- Unless it is directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all

active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.[4]

The provision of USP <797> allowing for immediate use should not be viewed as a workaround for the standards governing sterile product preparation. Failure to comply with these standards may result in unsanitary and unsafe conditions for patients.[5]

ADMINISTRATION

Upon receipt of an order for IV hydration therapy, an individual with appropriate training and experience[6], including an RN or LPN (consistent with the requirements of Wis. Admin. Code ch. N 6), may administer the treatment.

While the patient undergoes the IV administration, an RN should perform a nursing assessment of the patient including monitoring their vital signs. Please note that the performance of a nursing assessment is outside the scope of an LPN. An RN should monitor the patient for side effects, allergic reactions or any unusual or unexpected effects. An RN is expected to document all nursing acts performed by the RN as part of the administration and monitoring of the patient.

CONCLUSION

The practices engaged in at IV hydration clinics involve the practice of multiple professions. Individuals engaged in these practices must hold the appropriate license and practice within the scope of practice allowed by their credentials. Licensees who fail to follow the laws governing their practice could be subject to disciplinary proceedings as appropriate.

Licensees are charged with protecting the public by ensuring their practice complies with the laws and regulations of Wisconsin and any relevant federal regulations, including satisfying all applicable professional standards.

ACKNOWLEDGEMENT SECTION

These materials may have been consulted in the preparation of the above document.

ARIZONA STATE BOARD OF NURSING, *Advisory Opinion Intravenous Hydration and Other Therapies* (Revised date May 2024), Available at https://azbn.gov/sites/default/files/AO-IV-Hydration-Other-Therapies.pdf

[4] Handling of sterile hazardous drugs must comply with USP <800> as well.

[5] See FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-compounding-drug-products-medical-offices-and-clinics-under-insanitary

[6] For example, if an electrolyte is being administered by IV, the IV should be administered using a volumetric infusion pump or rate-controller tubing to ensure the electrolytes are administered at an appropriate rate to avoid and prevent adverse reactions. The individual administering the IV in this case should have training and experience using these devices.

KENTUCKY.GOV, *Joint Statement of the Kentucky Boards of Medical Licensure, Nursing, and Pharmacy Regarding Retail IV Therapy* (March 28, 2025), available at https://kbn.ky.gov/KBN%20Documents/Joint%20Statement%20-%20IV%20Hydration%20Clinics.pdf

MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE, *Guidance Regarding IV Hydration Therapy from the Mississippi State Board of Medical Licensure* (Sept. 5, 2023), available at https://www.msbml.ms.gov/sites/default/files/news/IV%20Hydration%20Therapy%20Guidance%2009-05-23.pdf

NEBRASKA BOARD OF NURSING, *Advisory Opinion: IV/Infusion Therapy* (Nov. 2023), available at https://dhhs.ne.gov/licensure/Documents/IVInfusion.pdf

OHIO BOARD OF PHARMACY, *Joint Regulatory Statement of the State Medical Board of Ohio, Ohio Board of Pharmacy, and Ohio Board of Nursing Regarding Retail IV Therapy* (May 15, 2025), available at https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/joint%20regulatory%20statement%20on%20the%20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf

RHODE ISLAND DEPARTMENT OF HEALTH, *Rhode Island Department of Health Guidance Document Regarding the Operation of Medical Spas and Intravenous (IV) Therapy Businesses* (July 2024), available at https://health.ri.gov/sites/g/files/xkgbur1006/files/publications/guidance/Medical-Spa-and-IV-Therapy-Business.pdf

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION, *Joint Advisory Opinion of the South Carolina State Boards of Medical Examiners, Pharmacy, and Nursing Regarding Retail IV Therapy Businesses* (Aug. 15, 2023), available at https://llr.sc.gov/med/Policies/Joint-Position-Statement-Retail-IV-Therapy.pdf